UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA *ex rel.* BROOK JACKSON, Plaintiff, v. VENTAVIA RESEARCH GROUP, LLC; PFIZER, INC.; ICON, PLC, Defendants.	)	Civil Action No.: 1:21-cv-00008-MJT

RELATOR'S SUR-REPLY TO GOVERNMENT'S LATE REPLY RE MOTION TO INTERVENE AND DISMISS

TO THE HONORABLE JUDGE OF THE COURT:

Relator Brook Jackson ("Relator") hereby requests that the Court consider this sur-reply to the late reply of the United States of America ("Government" or "DOJ") to Relator's opposition to the DOJ's motion to intervene to dismiss [ECF No. 137].

INTRODUCTION

In its effort to gain permission to intervene and dismiss this extraordinarily important False Claims Act case, the DOJ asserts several misleading half-truths. Yes, Brook Jackson's *qui tam* action is brought in the name of the Government and the United States is the real party in interest. But, in making the False Claims Act "the Government's primary litigative tool for combating fraud" "in modern times," S. Rep. No. 99-345, at 2, Congress partially assigned rights directly to relators like Brook Jackson, equipping them with authority to litigate *qui tam* claims without control or even direct participation of the DOJ. Brook Jackson does not need approval of the DOJ or agency executives to fulfill her role before this Court.

Yes, Congress provided in 31 U.S.C. § 3730(c)(3) a mechanism for the Government to file a motion seeking dismissal of the *qui tam* action notwithstanding a relator's objections. But, as the Supreme Court made clear, the Government first must show good cause to intervene to become a party to the action, and even then, the Government must "offer[] a reasonable argument for why the burdens of continued litigation outweigh its benefits." *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 143 S. Ct. 1720, 1734 (2023). Congress intended that False Claims Act claims be dismissed for legitimate government purposes, and not as a result of fraud, illegality, or lack of political will. S. Rep. 99-345, at 25-26. *See United States ex rel. Sequoia v. Sunland Packing House Co.*, 912 F. Supp. 1325, 1340 (E.D. Cal. 1995) (citing Senate Report)**,** *affirmed United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1146 (9th Cir. 1998); *In re Nat. Gas Royalties ex rel. United States v. Exxon Co., USA*, 566 F.3d 956, 963 (10th Cir. 2009) (noting the important role of relators in valid enforcement actions "even when the government should be on notice of the fraud" as the Government "could lack the resources (or, indeed, the political will) to pursue a claim").

And yes, the courts have, both before and after *Polansky*, found "good cause" for intervention under § 3730(c)(3) based on the Government's reason for moving to dismiss under § 3730(c)(2)(A), "itself." But in each and every case, the Government was able to show a reasoned basis for intervention and dismissal, grounded in a valid governmental purpose as exemplified in the Granston Memo. Mendenhall Exh. K. Never before has the DOJ sought to dismiss a meritorious case like Brook Jackson's case here, where the relator can demonstrate a strong basis to recover substantial damages for harms caused to the United States by fraud and false claims on the public fisc. And, never before has the Government failed to even articulate a legitimate reason for dismissal.

In its late reply, the DOJ waives key points and authorities raised in the opposition. The catastrophic harms caused by Pfizer's ineffective and unsafe modified RNA biologic, the loss of credibility in agencies and the DOJ as they abdicate public policy to partner up with corporate interests, and the essential role courts hold keeping our Government functioning in the face of executive failures, are all now undisputed. The DOJ continues to assert an unfettered right to dismiss any *qui tam* action whenever it wants, without mention of the Granston Memo. It offers no explanation for how this lawsuit seeking to hold Pfizer accountable for proven fraud in the design, conduct, analysis and reporting of the clinical trials is contrary to national health policy. The Government does not deny that dismissal would undermine the Act by sending a chilling signal to future relators that exposing fraud on the United States is futile when agency executives want that fraud kept secret. Nor does it deny that this is its true motive for seeking dismissal. The DOJ does not address Rule 24 of the Federal Rules of Civil Procedure, or the requirement under subdivision (d)(3) of that Rule that the Court consider prejudice to Brook Jackson as the original party in determining whether to grant permissive intervention. And, it completely ignores constitutional arguments regarding content-based infringement of Brook Jackson's First Amendment right to petition, the disordering of the separation of powers to protect corporate and executive actors, and the lack of a rational basis under due process and equal protection.

While the Government possesses the authority, indeed obligation, to make a "later date" intervention to dismiss *qui tam* actions on good grounds based on legitimate government purposes consistent with the False Claims Act, no such showing is made here. The DOJ's motion should be denied without prejudice on this record. In the event that the Government seeks to intervene post-seal period based on actual evidence and articulated grounds, the Court should allow limited discovery and hold an evidentiary hearing under § 3730(c)(2)(A) and (c)(3).

SUR-REPLY ARGUMENTS

I. The DOJ Failed to Show Good Cause for Intervention

Contrary to the DOJ's contention, no court has ever relieved the DOJ of the obligation to make a showing of good cause for a "later date" intervention under § 3730(c)(3). Every court which has found good cause to intervene based on the Government's motion to dismiss did so because the Government had a reasonable basis for seeking dismissal: *i.e.*, the Government "offer[ed] a reasonable argument for why the burdens of continued litigation outweigh its benefits." *Polansky*., 143 S. Ct. at 1734. And, since the Supreme Court in *Polansky* rejected the DOJ's assertion of unfettered discretion to dismiss, no Court has held that the government's mere assertion of the motion, itself, satisfied good cause. In each, it was the substantive reason for the dismissal, itself, that provided good cause. The assertion of an unfettered discretion here fails to provide good cause.

Polansky provides a perfect example. In discussing the good cause finding by the Third Circuit, the Supreme Court stated the actual grounds for seeking dismissal, not the mere assertion of the unfettered right, as showing good cause.

> And applying that standard, the Third Circuit found that the Government's request to dismiss the suit—based on its weighing of discovery burdens against likelihood of success—itself established good cause to intervene. *See* [17 F.4th 376, 392-393 (3d Cir. 2021)]. [*Polanksy*, 143 S. Ct. at 1729.]

As pointed out in the opposition but ignored in the reply, these reasons for dismissal included evidence that actual "discovery burdens mounted and weighty privilege issues emerged," and the Government had "thoroughly investigated the cost and benefits of allowing [Polansky's] case to proceed and ha[d] come to a *valid* conclusion based on the results of its investigation." 143 S. Ct. at 1729 (emphasis supplied). "Polansky [did] not challenge that conclusion." *Id*. No such showing is made by the DOJ here.

Similarly, the DOJ ignores the actual basis for dismissal established in *Brutus Trading, LLC v. Standard Chtd. Bank*, 2023 U.S. App. LEXIS 21868, at *5 (2d Cir. Aug. 21, 2023). There, the Government showed that the relator's "factual allegations were unsupported, its legal theory was not cognizable, and the continuation of the suit would waste considerable government resources." Contrary to the DOJ's position here, it was not the mere assertion of an unfettered right to dismiss that established good cause.

In *United States ex rel. Carver v. Physicians Pain Specialists of Ala., P.C.*, 2023 U.S. App. LEXIS 19592, at *11-13 (11th Cir. July 31, 2023), it was the "same *grounds*" supporting dismissal that also established good cause, not the mere assertion of a right. (Emphasis supplied.) Those grounds included evidence that Carver had "failed to prosecute this action to an enforceable judgment, neglected her responsibilities as a relator, burdened the United States with discovery requests that are either irrelevant or premature, and undercut the United States' FCA enforcement efforts in this district." *Id*. The DOJ in *Carver* provided great detail for these considerations, showing that "it did not make the decision 'lightly,' [and] it had 'determined that the costs of continued litigation outweigh any benefits the United States could realistically obtain.'" No such claims could be made in connection with Brook Jackson's lawsuit here.

In *United States. ex rel. USN4U, LLC v. Wolf Creek Fed. Servs.*, 2023 U.S. Dist. LEXIS 217620, at *4-5 (N.D. Ohio Dec. 7, 2023), the district court expressly found that the Government had "shown good cause to intervene." In *Wolf Creek*, the district court held:

> Here, for good cause the U.S. contends that discovery has cast doubt on the Relator's ability to prove any False Claims Act violations against Defendants. Many of the Relator's allegations and his expert's opinions have been challenged by the testimony of the NASA employees who were deposed in this case. For example, Relator argues that NASA employees did not adequately review Defendants' proposals, but the NASA employees described a lengthy review process for the approval of the proposals. And the U.S. correctly questions the ability of Relator's expert to refute this because he was not involved in NASA's

> review process. See ECF Doc. 69-1 at 7. The U.S. also shares the concerns of [*5] the Court regarding Relator's credibility; his testimony during the October 4, 2023 hearing was "vague, evasive and contradictory." Id. The U.S. does not want to devote any more resources to the case given the unlikelihood of Relator's success. [*Id*.]

The district cour's decision t is currently being appealed, mainly on other grounds. But even this ruling supports Brook Jackson here, as the DOJ fails to point to any of the factors that were found to be present there.

The DOJ disingenuously accuses Relator of asserting that courts "look beyond the flexible 'good cause' standard." *See* DOJ Reply, at 3. In fact, Relator acknowledges and embraces the good cause standard. Despite its flexible, familia and non-burdensome nature, the Government simply does not meet it. Similarly, the DOJ claims that it is not required to ground its "later date" intervention on "new evidence" or "changed circumstances," *id*., but it cites no authority in that regard. In contrast, Relator in her opposition quotes the Supreme Court's decision in *Polansky* explaining Congress's purpose for "good cause" later date permissive intervention, because it "knew circumstances could change and new information could come to light." *Polansky,* 143 S. Ct. at 1733. *See* Relator's Opp., at 13-14.[1] In sum, none of the courts since *Polansky* have agreed that the DOJ has unfettered authority to intervene to dismiss *qui tam* actions. Neither the language nor the purpose of the *qui tam* provisions support the government assertion of that position here.

II. The DOJ Failed to Address Brook Jackson's Constitutional Arguments

The DOJ makes little effort to address the detailed constitutional arguments presented in the opposition. *See* DOJ Reply, at 3-4. In order to evade its obligation to act consistent with constitutional constraints, the DOJ suggests that Brook Jackson may petition the government

[1] Relator inadvertently did not place this quote from *Polansky* in block-quote form.

elsewhere – through some "other appropriate avenues" – to raise "concerns about federal agency decision-making." DOJ Reply, at 3. The Government does not deny that Congress partially assigned to Relator the right to petition the Government for redress of the *Goverenment's injury*. Nor does the Government refute that it would be a violation of the First Amendment to infringe on Brook Jackson's speech in the public square based upon her viewpoint that Pfizer committed clinical trial fraud to the injury of the United States and its People. And thus, the DOJ offers no explanation for how this content-based restriction of her right to petition under the *qui tam* statute complies with the First Amendment.

Worse, the DOJ completely ignores the point raised in the opposition that separation of powers concerns must weigh heavily in the "good cause" determination. *See* Relator's Opp., at 21-22; *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, 970 F.3d 835, 847 (7th Cir. 2020) *(*"avoiding offense to the separation of powers in a case that actually risks it would itself weigh heavily in any 'good cause' determination"). Here, the DOJ's motion to dismiss should be carefully and independently reviewed by this Article III Court, as the Government attempts to rewrite both the objective standards in EUA statute *and* the 1986 False Claims Act amendments which eliminated the "government knowledge" bar. Government knowledge, acquiescence or complicity in Pfizer's clinical trial fraud would not excuse the sponsor of its obligations to conduct non-fraudulent trials on its biologic product. In these circumstances, the Court is the last bastion of hope for a Government that adheres to the Rule of Law.

Finally, the DOJ does not dispute, and therefore concedes, that substantive due process and equal protection require that its motion have a rational basis. The Government's abject failure to make a coherent explanation for dismissal means it fails even this minimal test. There can be no doubt that protection of whistleblowers is a principal policy of the United States. So

too is prevention of fraud in the design, conduct, analysis and reporting of clinical trials. Given this, the DOJ is unable to explain to the Court, or the People, why Brook Jackson's prosecution of this action is inconsistent with national policy. Rather, dismissal of this case, would be.

CONCLUSION

The Court should grant leave to file this sur-reply, and deny the DOJ's motion to intervene and dismiss for the reasons stated herein, in the opposition and at oral argument.

Date: April 30, 2024

Respectfully submitted,

/s/ Jeremy L. Friedman

Jeremy L. Friedman, CA Bar No. 142659
LAW OFFICE OF JEREMY L. FRIEDMAN
2801 Sylhowe Road.
Oakland, Ca. 94610
Tel: (510) 530-9060
Fax: (510) 530-9087
Email: jlfried@comcast.net

Warner Mendenhall, OH Bar No. 70165
MENDENHALL LAW GROUP
190 North Union Street, Suite 201
Akron, OH 44304
Tel: (330) 535-9160; Fax: (330) 762-9743
Email: warner@warnermendenhall.com

Lexis Anderson, Esq.
Robert E. Barnes, Esq., *Admitted Pro Hac Vice*
Member Eastern District of Texas,
TX State Bar No. 24127016
BARNES LAW
700 South Flower Street, Suite 1000
Los Angeles, California 90017
Tel: (310) 510-6211; Fax: (310) 510-6225
Email: robertbarnes@barneslawllp.com
Email: lexisanderson@barneslawllp.com

Counsel for Relator Brook Jackson

CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of April 2024 a true and correct copy of the foregoing document was filed electronically in compliance with Local Rule CV-5. All counsel of record consented to electronic service and are being served with a copy of this document through the Court's CM/ECF system under Local Rule CV-5(a)(3)(A).

/s/ Jeremy L. Friedman